



NBAC Facts

Ethical and Policy Issues in International Research

Issue

How to adequately protect the rights and welfare of individuals who participate in clinical trials is emerging as a critical issue in international research ethics. In the past decade, there has been a significant increase in the amount of clinical research that the U.S. conducts or sponsors in other countries, particularly in countries that are resource poor.

The increasing globalization of the biomedical and behavioral research enterprise holds much promise for developing treatments that prevent illness, improve health and cure disease. At the same time, this growth is raising concerns about whether existing regulations and guidelines can provide sufficient ethical standards to prevent harm to research participants while allowing important research to proceed. This is particularly relevant in the international arena, where circumstances under which research is being conducted markedly differ from those under which domestic research is conducted.

The National Bioethics Advisory Commission (NBAC) has spent the past several months discussing a variety of issues related to international clinical research. By late spring of 2000, the Commission expects to produce a report that will address the ethical, legal, and policy issues that arise when the U.S. funds or conducts research in other countries. NBAC's goal is to identify these issues and determine whether they are unique to international settings and deserve special attention from policymakers. NBAC will be looking at recruitment of subjects, informed consent, and the risks and potential benefits of conducting research. The Commission also will focus on the obligations of researcher sponsors to research participants, communities, and countries before, during, and after a trial. The report will consider how and to what extent cultural and other factors influence these issues. Finally, NBAC will be analyzing many national and international guidelines and statements to make recommendations about possible ways to enhance international collaborative research.

Background

NBAC has been examining the issue of human subjects protection since its establishment by the President in late 1995. A number of factors have prompted its focus on international research at this time. One of the most significant has been the recent ethical debate over the merits of using placebo-controlled trials of AZT or zidovudine to prevent mother-to-infant transmission of HIV infection in West Africa.

National Bioethics Advisory Commission

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Another factor relates to the changing picture of international research. Increasingly, physicians, epidemiologists, and other developing country researchers are collaborating in research.

Also, there has been an increase in the amount of research conducted by private companies and their market-oriented approach has created pressure to be efficient in the pursuit of research.

NBAC's international project is being undertaken at the same time that two influential international groups are in the process of revising their principles on research ethics related to human subjects. The World Medical Association is now revising the 35-year-old Declaration of Helsinki. The Geneva-based Council for International Organizations of Medical Sciences (CIOMS) also is revising its guidelines for the ethical conduct of research projects.

Questions the Commission Will Answer

- What are the obligations of U.S. research sponsors when international guidelines include requirements that are not included in U.S. regulations?
- Do current U.S. regulations regarding informed consent pose a barrier to the conduct of research in some countries?
- What collaboration procedures should be followed between research sponsor and host country?
- What is owed to research subjects during a clinical trial and after completion of the research? Is it obligatory to provide treatment that is equivalent to that which would be provided in the sponsoring country?
- How can researchers overcome or address problems in a culturally sensitive way without compromising the ethical standards of research?
- How can independent ethical review of research projects be ensured in countries that have relatively little past experience in scientific research or lack expertise in the basic precepts of research ethics?
- How can the U.S. help ensure the achievement of global justice in the conduct of international research?

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The National Bioethics Advisory Commission (NBAC) was established by Executive Order 12975 in October 1995 to advise the National Science and Technology Council and other appropriate government entities regarding bioethical issues arising from research on human biology and behavior. NBAC's first priority as directed in its Executive Order, was to "consider the protection of the rights and welfare of human research subjects; and issues in the management and use of genetic information." The Executive Order encouraged NBAC to identify other bioethical issues for the purpose of providing advice and recommendations. Chaired by Princeton University President Harold T. Shapiro, Ph.D., the Commission is comprised of physicians, theologians, ethicists, scientists, lawyers, psychologists, and mental health advocates.

For more information on this project and other NBAC activities, call (301) 402-4242 (phone) or (301) 480-6900 (fax) or visit our web site at www.bioethics.gov.